

CABINET FOR HEALTH AND FAMILY SERVICES
Office of Inspector General
Division of Health Care
(Amendment)

906 KAR 1:110. Critical access hospital services.

RELATES TO: KRS 205.639(3), 211.842-211.852, 216.378, 216.379, 216.380, ~~[216B.040,]~~ 216B.015(6), 216B.040(1)(c), (2)(b), ~~[216B.042, 216B.045-216B.055, 216B.075,]~~ 216B.105, 216B.153, 216B.165, 216B.990, Chapter ~~[216B.115-216B.131,]~~ 311, 315.035, 333.030, ~~[315, 333,]~~ 42 C.F.R. 485.601-42 C.F.R. 485.647, 45 C.F.R. Part 160, Part 164, 42 U.S.C. 1320d-2—1320d-8, 42 U.S.C. 1395i-4(c)(2)~~[485.644]~~

STATUTORY AUTHORITY: KRS 216.380(14), ~~[216B.040(3)(a),]~~ 216B.042(1)(a), (c)~~[, 42 U.S.C. 1395i-4]~~

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216.380(14) requires the Cabinet for Health and Family Services to promulgate administrative regulations necessary to implement a program for the licensure of critical access hospitals. KRS 216B.042(1)(a) and (c) require the cabinet to promulgate administrative regulations necessary for the proper administration of the licensure function and to establish licensure standards and procedures to ensure safe, adequate, and efficient health facilities and health services. This administrative regulation establishes quality of care and licensure standards for critical access hospitals.

Section 1. Definitions. (1) "Cabinet" is defined by KRS 216B.015(6)~~[(5)]~~.

(2) "Licensee" means the entity that has been issued and holds a valid critical access hospital license from the cabinet ~~[for Health and Family Services]~~.

Section 2. Requirements for Critical Access Status. (1) An applicant for initial licensure of a critical access hospital shall provide documentation to the cabinet verifying that the hospital:

(a) Complies with the requirements of KRS 216.380 and this administrative regulation~~[(3) or (4) have been met]; and~~

(b) ~~[The hospital]~~ Qualifies for state designation under 42 U.S.C. ~~[Section]~~ 1395i-4(c)(2)~~]; and~~
~~—(c) The requirements of this administrative regulation have been met].~~

(2) In accordance with 42 U.S.C. 1395i-4(c)(2)(B), a critical access hospital that was certified by the secretary of the cabinet as a necessary provider of services prior to January 1, 2006, may be relicensed as a critical access hospital ~~if[, provided]~~ the requirements of this administrative regulation are met.

(3)~~(a)~~ If an application for initial licensure of a critical access hospital is denied by the cabinet, the applicant shall be entitled to an administrative hearing pursuant to KRS 216B.040(1)(c) and (2)(b), and KRS 216B.105~~[Chapter 13B]~~.

~~(b)~~ Licensure hearings shall follow the procedures established by~~[in]~~ 900 KAR 6:040.

Section 3. Administration and Operation. (1) The licensee shall be legally responsible for the operation of the critical access hospital and for compliance with federal, state, and local laws and administrative regulations~~[law]~~ pertaining to the operation of the critical access hospital.

(2) A critical access hospital shall be under the medical direction of a physician licensed to practice medicine or osteopathy in Kentucky.

(3) The licensee shall:

(a) Establish written policies and lines of authority; and

(b) Designate an administrator as the person principally responsible for the daily operation of

the critical access hospital.

(4) The licensee shall develop patient care policies with the advice of a group of healthcare professionals ~~[professional persons, as]~~ identified by the licensee.

(a) Pursuant to 42 C.F.R. 485.635(a)(2), the advisory group ~~[of professional persons]~~ shall include:

1. At least one (1) Kentucky-licensed doctor of medicine or doctor of osteopathic medicine~~[or more physicians licensed in the Commonwealth of Kentucky]; and~~

2. One (1) or more physician assistants, advanced registered nurse practitioners, or clinical nurse specialists~~[persons who are not members of the staff].~~

(b) The patient care policies shall include:

1. A description of services that the critical access hospital furnishes, including services provided ~~[shall provide directly or]~~ through a contractual agreement;

2. A written program narrative describing in detail the:

a. Services ~~[to be]~~ offered;

b. Methods and protocols for service delivery;

c. Qualifications of personnel ~~[to be]~~ involved in the delivery of services; and

d. Outcomes expected to be attained through the delivery of specified services;

3. Guidelines for the medical [case] management of health problems, including~~[which include]~~:

a. Criteria for determining if a case requires medical consultation;

b. Patient referral procedures; and

c. Maintenance of health records;

4. Procedures for the proper storage, handling, and administration of drugs and biologicals; ~~[and]~~

5. Procedures establishing annual review and evaluation of services provided;

6. Procedures that assure the reporting and investigation of quality of care and safety problems in accordance with KRS 216B.165, including assurance that retaliatory action shall not be taken against a staff member who in good faith reports a patient care or safety problem; and

7. A surgical smoke safety and control policy that shall be available to staff if the hospital offers any surgical procedure that is likely to produce surgical smoke.

(5) A critical access hospital shall establish written policies regarding patient rights and responsibilities ~~to~~~~[-The policies shall]~~ assure that each patient is:

(a) Informed of:

1. Patient rights;

2. Rules and regulations governing patient conduct and responsibilities; and

3. The procedure for handling a patient grievance;

(b) Informed of services available and related charges, including charges not covered by Medicare, Medicaid, or other third-party payor;

(c) Informed of the patient's:

1. Medical condition, unless medically contraindicated as documented in the patient's medical record;

2. Right to participate in planning his or her medical treatment; and

3. Right to refuse to participate in experimental research;

(d) Assisted in understanding his or her patient rights;

(e) Provided confidential treatment of his or her records in accordance with subsection (9) of this section~~[and given the opportunity to approve or refuse their release to an individual not involved in his or her care, except as required by Kentucky law or third-party payment contract];~~

(f) Treated with consideration, respect, and recognition of the patient's dignity and individuality, including privacy in treatment and care of personal health needs; and

(g) Informed of the procedure for filing a grievance or a recommendation to change a policy or service. The policy shall establish a time frame within which critical access hospital personnel shall determine what corrective action to take.

(6) Personnel.

(a) Staffing shall be maintained in accordance with KRS 216.380(9).

(b) A physician shall:

1. Be responsible for all medical aspects of the critical access hospital;
2. Provide direct medical services in accordance with KRS Chapter 311;
3. Be present to provide medical direction, supervision, and consultation to ~~[the]~~ staff at least once in every two (2) week period, unless no patient has been treated since the last visit;
4. Participate with other medical personnel in developing, executing, and periodically reviewing written policies and services;
5. Review and sign patient records during the site visit; and
6. Provide medical orders and medical care services to patients in accordance with the critical access hospital's ~~[hospital]~~ protocols.

(c) A registered nurse or licensed practical nurse shall be on duty if a patient has been admitted for overnight stay.

(7) The critical access hospital shall have transfer and linkage contracts in accordance with ~~[that meet the requirements of]~~ KRS 216.380(11) and (12).

(8) Medical records.

(a) A critical access hospital shall maintain a complete, comprehensive, accurate, and legible medical record for each patient. The ~~[records. A medical]~~ record shall include ~~[contain at least]~~ the following information:

1. The names of the patient's immediate family members;
2. Medical and social history, including information ~~[data]~~ obtainable from other providers;
3. Description of each medical visit or contact, including:
 - a. Condition or reason necessitating visit or contact;
 - b. Assessment;
 - c. Diagnosis;
 - d. Services provided;
 - e. Medications and treatments prescribed; and
 - f. Disposition made;
4. Reports of laboratory, x-ray, and other test findings; and
5. Documentation of referrals ~~[made]~~, including:
 - a. Reason for the referral;
 - b. To whom patient was referred; and
 - c. Information obtained from the referral source.

(b) Confidentiality of individual patient records shall be maintained in accordance with subsection (9)(b) of this section~~[at all times]~~.

(c) Transfer of records. The critical access hospital shall:

1. Establish systematic procedures to assist with ~~[in]~~ continuity of care if a ~~[the]~~ patient transfers to another licensed level of care; [moves to another source of care;] and
2. ~~[shall,]~~ Upon proper release, transfer medical records or an abstract upon request.

(d) Retention of records. Medical records shall be retained for at least:

1. Six (6) years from the date of ~~[After a patient's death or]~~ discharge; or
2. ~~[, the completed medical record shall be placed in an inactive file and retained for five (5) years or,]~~ If the patient is a minor, three (3) years after the patient reaches the age of majority under state law, whichever is the longest.

(9)(a) Ownership.

1. Medical records shall be the property of the critical access hospital.
2. The original medical record shall not be removed from the critical access hospital except by court order or subpoena.

3. Copies of a medical record or portions of the record may be used and disclosed. Use and disclosure shall be as established by paragraph (b) of this subsection.

(b) Confidentiality and Security: Use and Disclosure.

1. The critical access hospital shall maintain the confidentiality and security of medical records in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164, as amended, including the security requirements mandated by subparts A and C of 45 C.F.R. Part 164, or as provided by applicable federal or state law.

2. The critical access hospital may use and disclose medical records. Use and disclosure shall be as established or required by HIPAA, 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164, or as established in this administrative regulation.

3. A critical access hospital may establish higher levels of confidentiality and security than required by HIPAA, 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164.

(10) Utilization review and medical audit. In order to determine the appropriateness of services delivered, there shall be a written plan for utilization review that [which] specifies the frequency of reviews and composition of the body conducting the review.

(11)[(40)] Quality assessment and performance improvement program.

(a) Pursuant to KRS 216.380(10), a critical access hospital shall have a program[~~in accordance with KRS 216.380(10),~~] to ensure continuous and effective mechanisms for:

1. Review and evaluation of patient care; and
2. Corrective action.

(b) The quality assessment and performance improvement program shall:

1. Be approved by the licensee;
2. [~~Be~~]

~~(c) The program shall:~~

- 4.] Establish responsibility for the monitoring and evaluation of services;
- 3.[2.] Delineate the scope of care;
- 4.[3.] Identify specific aspects of care to be provided;
- 5.[4.] Establish and document clinical criteria used to monitor care and services;
- 6.[5.] Systematically evaluate the standard of care to identify problems and recommend corrective action or alternatives to improve the standard of care;
- 7.[6.] Establish criteria to assess the effectiveness of corrective action taken to improve care; and
- 8.[7.] Require documentation of improvements in the standard of care[~~]~~ subsequent to corrective action taken.

(12) Contract[

~~(11) Contracted]~~ services. The critical access hospital shall assure that a service provided under contract is properly licensed or certified in accordance with applicable local, state, and federal regulations and statutes.

Section 4. Provision of Services. (1) A critical access hospital shall provide ~~[the]~~ services in accordance with KRS 216.380(5).

(2) Laboratory services.

(a) A critical access hospital shall provide[~~either directly or through contract,~~] basic laboratory services essential to the immediate diagnosis and treatment of each [the] patient.

(b) If the critical access hospital provides laboratory services directly, the hospital [service]

shall comply ~~[be in compliance]~~ with 902 KAR 20:016, Section 4(4).

(c) If the critical access hospital contracts for laboratory services, the laboratory shall be licensed pursuant to KRS 333.030~~[it contracts with shall be in compliance with KRS Chapter 333].~~

(d) The following services shall be provided:

1. Chemical examination of urine, including ketone measurement, by stick or tablet method, or both;

2. Microscopic examination of urine sediment;

3. Hemoglobin or hematocrit;

4. Blood glucose~~[sugar]~~;

5. Examination of stool specimens for occult blood;

6. Pregnancy tests; and

7. Primary culturing for transmittal to a hospital laboratory or licensed laboratory.

(3) Emergency services.

(a) A critical access hospital shall:

1. Provide medical emergency procedures as a first response to common life-threatening injuries and acute illness;

2.~~[, and shall]~~ Have available ~~[the]~~ drugs and biologicals commonly used in life-saving procedures, such as analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids; and

3. Provide ~~[-~~

(a) examination services ~~[shall be provided by the critical access hospital]~~ in accordance with 902 KAR 20:012.

(b) There shall be a physician, nurse practitioner, or physician assistant with training or experience in emergency care:

1. On-call and immediately available by telephone or radio contact~~[-]~~ and

2. Available on site within thirty (30) minutes on a twenty-four (24) hour per-day basis.

(c) A registered nurse shall be on duty at the hospital to provide immediate emergency care on a twenty-four (24) hour per day basis.

(4) Pharmacy services.

(a) In accordance with KRS 216.380(5)(b), a critical access hospital shall provide~~[-, either directly or through contract,]~~ basic pharmacy services essential to the treatment of the patient.

(b)~~[(a)]~~ If the critical access hospital provides pharmacy services directly, the hospital shall comply ~~[it shall be in compliance]~~ with 902 KAR 20:016, Section 4(5).

(c)~~[(b)]~~ If the critical access hospital contracts for pharmacy services, the pharmacy shall have a permit to operate in accordance with KRS 315.035~~[it contracts with shall be in compliance with KRS Chapter 315].~~

(5) Radiology services.

(a) In accordance with KRS 216.380(5)(b), a critical access hospital shall provide~~[-, either directly or through contract,]~~ basic radiology services essential to the immediate diagnosis and treatment of the patient.

(b)~~[(a)]~~ If the critical access hospital provides radiology services directly, the hospital shall comply ~~[it shall be in compliance]~~ with 902 KAR 20:016, Section 4(6).

(c)~~[(b)]~~ If the critical access hospital contracts for radiology services, the radiology facility shall be currently licensed or registered ~~[service it contracts with shall have a current license or registration]~~ pursuant to KRS 211.842 to 211.852.

(6) Dietary services. Pursuant to KRS 216.380(5)(b), the critical access hospital shall provide dietary services ~~[shall be provided either]~~ directly or by contract~~[-]~~ in accordance with 902 KAR 20:016, Section 4(3) to each~~[-, if a]~~ patient who is admitted to the ~~[critical access]~~ hospital and remains for more than twelve (12) hours.

(7) Psychiatric units. A critical access hospital that provides inpatient psychiatric services in a distinct part ~~[has established a psychiatric]~~ unit in accordance with KRS 216.380(7)(a)[,] shall comply ~~[be in compliance]~~ with 902 KAR 20:180.

(8) Rehabilitation units. A critical access hospital that provides inpatient ~~[has established a]~~ rehabilitation services in a distinct part unit in accordance with KRS 216.380(7)(b)[,] shall comply ~~[be in compliance]~~ with the requirements of 902 KAR 20:240.

(9) Surgical services.

(a) If a critical access hospital provides surgical services, the hospital shall comply with 42 C.F.R. 485.639.

(b) 1. In accordance with KRS 216B.153, a critical access hospital that utilizes an energy-generating device shall make use of a smoke evacuation system:

a. That effectively captures and neutralizes surgical smoke at the site of origin and before the smoke can make ocular contact or contact with the respiratory tract of the occupants of the room; and

b. During any surgical procedure that is likely to produce surgical smoke.

2. The cabinet shall impose fines in accordance with KRS 216B.990(8) for each violation of noncompliance with KRS 216B.153 only if the violation has not been remedied after the hospital has had an opportunity to correct the violation through the filing of a plan of correction in accordance with 902 KAR 20:008, Section 2(13).

Section 5. Physical and Sanitary Environment. A critical access hospital shall maintain the condition of the physical plant and hospital's overall environment in accordance with ~~[comply with the provisions of]~~ 902 KAR 20:016, Section 3(10).

Section 6. Facility Requirements. A critical access hospital shall comply with the applicable structural specifications and physical plant requirements established by ~~[of]~~ 902 KAR 20:009 for ~~[related to the]~~ services offered.

ADAM MATHER, Inspector General

ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: November 12, 2021

FILED WITH LRC: December 28, 2021 at 8:30 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on March 21, 2022, at 9:00 a.m. using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this virtual hearing shall notify this agency in writing by March 14, 2022, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends virtually will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until March 31, 2022. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: Kara Daniel; Stephanie Brammer-Barnes; Krista Quarles

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the minimum licensure requirements for the operation of and services provided by critical access hospitals.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with the requirements of KRS 216.380(14) to implement a program for the licensure of critical access hospitals. This administrative regulation is also necessary to comply with KRS 216B.042(1), which requires the Cabinet for Health and Family Services to establish licensure standards and procedures to ensure safe, adequate, and efficient health facilities and health services.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of KRS 216.380 and 216B.042(1) by establishing the minimum licensure requirements for the operation of and services provided by critical access hospitals.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of the statutes by establishing the minimum licensure requirements for the operation of and services provided by critical access hospitals.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This amendment is required by KRS 216B.153, a new law created by the passage of SB 38 from the 2021 session of the Kentucky General Assembly. KRS 216B.153(2) directs the cabinet to promulgate administrative regulations to require a health facility that utilizes energy generating devices to make use of a smoke evacuation system during any surgical procedure that is likely to produce surgical smoke. In addition, this amendment makes technical changes to conform to the administrative regulation drafting requirements of KRS Chapter 13A to improve clarity and flow, and also makes general housekeeping changes.

(b) The necessity of the amendment to this administrative regulation: This amendment is required by KRS 216B.153(2).

(c) How the amendment conforms to the content of the authorizing statutes: This amendment conforms to the content of KRS 216B.153 by creating a requirement for critical access hospitals to make use of a smoke evacuation system during any surgical procedure that is likely to produce surgical smoke.

(d) How the amendment will assist in the effective administration of the statutes: This amendment will assist in the effective administration of the statutes by adding a requirement for surgical smoke evacuation systems pursuant to KRS 216B.153.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This amendment affects critical access hospitals that provide surgical procedures that are likely to produce surgical smoke. There are currently 27 critical access hospitals licensed in Kentucky.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Critical access hospitals will be required to make use of a smoke evacuation system during any surgical procedure that is likely to produce surgical smoke.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3). If a critical access hospital does not currently have a smoke evacuation system, the facility will incur costs associated with the purchase of a system if the hospital offers any surgical procedure that is likely to produce surgical smoke.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Surgical smoke generated by the use of an energy-generating device during a surgical procedure contains toxic and biohazardous substances that present risks to perioperative team members and patients. Therefore, the use of smoke evacuation equipment required by this amendment will protect health care workers and patients from the harmful effects of surgical smoke.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: There are no additional costs to the Office of Inspector General for implementation of this amendment.

(b) On a continuing basis: There are no additional costs to the Office of Inspector General for implementation of this amendment on a continuing basis.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The source of funding used for the implementation and enforcement of the licensure function is from federal funds and state matching funds of general and agency appropriations.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding is necessary to implement this amendment.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This amendment does not establish or increase any fees.

(9) TIERING: Is tiering applied? Tiering is not applicable as compliance with this administrative regulation applies equally to all critical access hospitals regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation affects Kentucky-licensed critical access hospitals. This administrative regulation also impacts the Cabinet for Health and Family Services, Office of Inspector General.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 216.380, 216B.042, 216B.153

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? Although KRS 216B.990(8) authorizes the cabinet to impose a fine ranging from \$100 to \$500 for each violation of KRS 216B.153, the cabinet is unable to predict with accuracy how many violations may be cited or otherwise determine the amount of fines that may be collected.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years?

The cabinet is unable to predict with accuracy how many violations may be cited or otherwise determine the amount of fines that may be collected.

(c) How much will it cost to administer this program for the first year? This amendment imposes no additional costs on the administrative body.

(d) How much will it cost to administer this program for subsequent years? This amendment imposes no additional costs on the administrative body during subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

FEDERAL MANDATE ANALYSIS COMPARISON

(1) Federal statute or regulation constituting the federal mandate. 42 C.F.R. 485.601-485.647, 45 C.F.R. 160, 164, 42 U.S.C. 1320d-2 - 1320d-8, 42 U.S.C. Section 1395i-4(c)(2)

(2) State compliance standards. KRS 216.380, 216B.042

(3) Minimum or uniform standards contained in the federal mandate. 42 C.F.R. 485.601-485.647 establish the federal conditions of participation for the certification of critical access hospitals.

45 C.F.R. 160, 164, and 42 U.S.C. 1320d-2 – 1320d-8 establish the HIPAA privacy rules to protect individuals' medical records and other personal health information.

42 U.S.C. Section 1395i-4(c)(2) establishes the criteria for designation as a critical access hospital.

(4) Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? This administrative regulation does not impose requirements that are more strict than federal laws or regulations.

(5) Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. Not applicable.